

## General

#### Guideline Title

Clinical assessment following acute cervical spinal cord injury. In: Guidelines for the management of acute cervical spine and spinal cord injuries.

### Bibliographic Source(s)

Hadley MN, Walters BC, Aarabi B, Dhall SS, Gelb DE, Hurlbert RJ, Rozzelle CJ, Ryken TC, Theodore N. Clinical assessment following acute cervical spinal cord injury. In: Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery. 2013 Mar;72(Suppl 2):40-53. [117 references] PubMed

#### Guideline Status

This is the current release of the guideline.

## Recommendations

## Major Recommendations

The rating schemes used for the strength of the evidence (Class I-III) and the levels of recommendations (Level I-III) are defined at the end of the "Major Recommendations" field.

Recommendations

Neurological Examination

Level II

The American Spinal Injury Association (ASIA) international standards for neurological and functional classification of spinal cord injury (SCI) are recommended as the preferred neurological examination tool for clinicians involved in the assessment and care of acute spinal cord injury patients.

Functional Outcome Assessment

Level I

The Spinal Cord Independence Measure (SCIM) III is recommended as the preferred functional outcome assessment tool for clinicians involved in the assessment, care, and follow-up of patients with SCIs.

Pain Associated with SCI

Level I

The International Spinal Cord Injury Basic Pain Data Set (ISCIBPDS) is recommended as the preferred means to assess pain, including pain severity, physical functioning, and emotional functioning, among SCI patients.

#### Summary

A variety of injury classification schemes have been utilized to describe patients who have sustained SCIs. There are 2 general types of assessment scales, neurological examination scales and functional outcome scales. The most accurate and meaningful description of SCI patients, in the acute setting and in longitudinal follow-up, is that accomplished by using a neurological scale in conjunction with a functional outcome scale. Based on a contemporary evaluation and ranking of the medical evidence, the 2000 ASIA Standards is the most consistent, reliable, valid, and responsive scoring system for the neurological assessment of adult patients with acute SCI, to a high degree of scientific certainty. This recommendation is supported by Class II medical evidence.

The SCIM III, designed specifically to assess the functional abilities and impairment of patients with spinal cord lesions and SCI, is the functional outcome assessment tool with the greatest scientific validity, reliability, and sensitivity. This recommendation is supported by Class I medical evidence.

The assessment of pain among patients with SCI is important and should include an evaluation of pain severity, physical functioning, and emotional functioning. There are a number of pain assessment classification instruments that have been used in this patient population. The ISCIBPDS has the highest reliability and validity of any of the pain classification instruments and is recommended on the basis of Class I medical evidence.

#### **Definitions**:

Rating Scheme for the Strength of the Evidence: Modified North American Spine Society Schema to Conform to Neurosurgical Criteria as Previously Published and for Ease of Understanding and Implementation: Levels of Evidence for Primary Research Question<sup>a</sup>

Class	Therapeutic Studies: Investigating the Results of Treatment	Diagnostic Studies: Investigating a Diagnostic Test	Clinical Assessment: Studies of Reliability and Validity of Observations, Including Clinical Examination, Imaging Results, and Classifications
I	High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a Ä, statistic ≥0.60 or an intraclass correlation coefficient of ≥0.70
	Systematic review <sup>b</sup> of Class I randomized controlled trials (and study results were homogeneous <sup>c</sup> )	Systematic review <sup>b</sup> of Class I studies	
П	Lesser-quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization)	Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a Ä, statistic of 0.40–0.60 or an intraclass correlation coefficient of 0.50–0.70
	Prospective <sup>d</sup> comparative study <sup>e</sup>	Systematic review <sup>b</sup> of Class II studies	
	Systematic review <sup>b</sup> of Class II studies or Class I studies with inconsistent results	Study of nonconsecutive patients; without consistently applied reference "gold" standard	
	Case-control study <sup>g</sup>	Systematic review <sup>b</sup> of Class III studies	
	Retrospective <sup>f</sup> comparative study <sup>e</sup>	Case-control study	
	Systematic review <sup>b</sup> of Class II studies		

Hass	The Association of Studies: Investigating the Results of Treatment	Boor reference standard Diagnostic Studies: Investigating a Diagnostic Test	Evidence provided by lor more well-designed clinical structures of Relability and calidity structures of the structure of clinical examination, including clinical examination, reliability is represented by a Ä statistic of <0.40 or an intraclass correlation coefficient of <0.50
	Expert opinion	Expert opinion	

<sup>&</sup>lt;sup>a</sup>A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>e</sup>Patients treated 1 way (e.g., halo vest orthosis) compared with a group of patients treated in another way (e.g., internal fixation) at the same institution.

 ${}^{\mathrm{f}}$ The study was started after the first patient was enrolled.

<sup>g</sup>Patients identified for the study on the basis of their outcome, called "cases" (e.g., failed fusion), are compared with those who did not have outcome, called "controls" (e.g., successful fusion).

<sup>h</sup>Patients treated 1 way with no comparison group of patients treated in another way.

#### Levels of Recommendation

Level I	Generally accepted principles for patient management, which reflect a high degree of clinical certainty (usually this requires Class I evidence which directly addresses the clinical questions or overwhelming Class II evidence when circumstances preclude randomized clinical trials)
Level II	Recommendations for patient management which reflect moderate clinical certainty (usually this requires Class II evidence or a strong consensus of Class III evidence)
Level	Other strategies for patient management for which the clinical utility is uncertain (inconclusive or conflicting evidence or opinion)

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Acute cervical spine and spinal cord injuries

## Guideline Category

Evaluation

Management

<sup>&</sup>lt;sup>b</sup>A combination of results from 2 or more prior studies.

<sup>&</sup>lt;sup>c</sup>Studies provided consistent results.

<sup>&</sup>lt;sup>d</sup>Study was started before the first patient enrolled.

# Clinical Specialty Neurological Surgery

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Neurology

Orthopedic Surgery

#### **Intended Users**

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To help define the acute spinal cord injury (SCI) patient's neurological deficits and to facilitate communication about patient status to caregivers

## **Target Population**

Patients with acute cervical spine and spinal cord injuries (SCIs)

#### **Interventions and Practices Considered**

- 1. Neurological examination using the American Spinal Injury Association (ASIA) international standards
- 2. Functional outcome assessment using the Spinal Cord Independence Measure (SCIM) III
- 3. Pain assessment using the International Spinal Cord Injury Basic Pain Data Set (ISCIBPDS)

## Major Outcomes Considered

Reliability, validity, and sensitivity of clinical assessment scales and instruments

# Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Search Criteria

A computerized search of the database of the National Library of Medicine (PubMed) of the literature published from 1966 to 2011 was performed for each of the 3 subtopics reviewed in this guideline: neurological assessment, function outcome, and pain following spinal cord injury (SCI). The search was limited to the English language, the human literature, and reviews, case series, meta-analyses, and randomized clinical trials of adult patients published between 1966 and 2011. The term "spinal cord injury" was combined with the term "neurological assessment," yielding 1444 references. A second search using the terms "spinal cord injury" and "assessment scales" yielded 81 references. A third search employing the terms "spinal cord injury" and "assessment scales" yielded 351 citations. A search using "ASIA impairment scale" yielded 351 citations. A search using the terms "ASIA classification" and "spinal cord" yielded 113 references (total 2167).

For functional outcome, each PubMed database search was limited to the English language, the human literature, and reviews, case series, meta-analyses, and randomized clinical trials published between 2000 and 2010. Search terms "spinal cord injury" and "functional outcomes assessment" yielded 448 references. Search terms "spinal cord injury" and "functional outcome scales" yielded 28 citations. A search for "functional independence measure" revealed 190 citations (total 1798).

For pain following SCI, each PubMed database search was limited to the English language, the human literature, and reviews, case series, meta-analyses, and randomized clinical trials published between 1966 and 2010. Search terms "spinal cord injury" and "pain" resulted in 2093 references. Search terms "spinal cord injury" and "pain classification" yielded 91 citations. A search using the terms "spinal cord injury" and "pain assessment scales" produced 26 references. Search terms "spinal cord injury" and "pain assessment scale" resulted in 121 references (total 2,331).

The 733 references for neurological assessment, the 520 references for functional outcome, and the 1050 citations for pain following SCI were imported into a database, and duplicates were eliminated. Articles germane to each of the 3 topics were selected by reviewing their titles and abstracts. Additional references were culled from the reference lists of the remaining papers. Finally, members of the author group were asked to contribute articles known to them on the subject matter that were not found by other search means.

#### Number of Source Documents

- 733 references for neurological assessment, 22 of which are included in the evidentiary table in the original guideline document
- 520 references for functional outcome, 21 of which are included in the evidentiary table in the original guideline document
- 1050 citations for pain following spinal cord injury (SCI), 29 of which are included in the evidentiary table in the original guideline document

#### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Rating Scheme for the Strength of the Evidence: Modified North American Spine Society Schema to Conform to Neurosurgical Criteria as Previously Published and for Ease of Understanding and Implementation: Levels of Evidence for Primary Research Question<sup>a</sup>

Class	Therapeutic Studies: Investigating the Results of Treatment	Diagnostic Studies: Investigating a Diagnostic Test	Clinical Assessment: Studies of Reliability and Validity of Observations, Including Clinical Examination, Imaging Results, and Classifications
I	High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a $\ddot{\rm A}$ , statistic $\geq 0.60$ or an intraclass correlation coefficient of $\geq 0.70$
	Systematic review <sup>b</sup> of Class I randomized controlled trials (and study results were homogeneous <sup>c</sup> )	Systematic review <sup>b</sup> of Class I studies	
П	Lesser-quality randomized controlled trial (e.g., <80% follow-up, no	Development of diagnostic criteria on consecutive patients	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver

Class	blinding or improper randomization) Therapeutic Studies: Investigating the Results of Treatment	Ovith universally applied Diagnostic Studies Investigating reference "gold" standard) a Diagnostic lest	reliability is represented by a Arctatistic of 0.40-0.60 or an intraclass correlation coefficient of 0.50-0.70 or Observations, including clinical Examination,
	Prospective <sup>d</sup> comparative study <sup>e</sup>	Systematic review <sup>b</sup> of Class II	Imaging Results, and Classifications
		studies	
	Systematic review <sup>b</sup> of Class II studies or Class I studies with inconsistent results	Study of nonconsecutive patients; without consistently applied reference "gold" standard	
	Case-control study <sup>g</sup>	Systematic review <sup>b</sup> of Class III studies	
	Retrospective <sup>f</sup> comparative study <sup>e</sup>	Case-control study	
	Systematic review <sup>b</sup> of Class II studies		
Ш	Case series <sup>h</sup>	Poor reference standard	Evidence provided by 1 or more well-designed clinical studies in which interobserver and intraobserver reliability is represented by a Ä, statistic of <0.40 or an intraclass correlation coefficient of <0.50
	Expert opinion	Expert opinion	

<sup>&</sup>lt;sup>a</sup>A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>e</sup>Patients treated 1 way (e.g., halo vest orthosis) compared with a group of patients treated in another way (e.g., internal fixation) at the same institution.

<sup>g</sup>Patients identified for the study on the basis of their outcome, called "cases" (e.g., failed fusion), are compared with those who did not have outcome, called "controls" (e.g., successful fusion).

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Selected articles were carefully reviewed by the authors. Evidentiary tables were created (refer to the tables in the original guideline document) that reflected the strengths and weaknesses of each article.

On occasion, the assessed quality of the study design was so contentious and the conclusions so uncertain that the guideline authors assigned a lower medical evidence classification than might have been expected without such a detailed review. In every way, adherence to the Institute of Medicine's criteria for searching, assembling, evaluating, and weighing the available medical evidence and linking it to the strength of the recommendations presented in this document was carried out.

<sup>&</sup>lt;sup>b</sup>A combination of results from 2 or more prior studies.

<sup>&</sup>lt;sup>c</sup>Studies provided consistent results.

<sup>&</sup>lt;sup>d</sup>Study was started before the first patient enrolled.

<sup>&</sup>lt;sup>f</sup>The study was started after the first patient was enrolled.

<sup>&</sup>lt;sup>h</sup>Patients treated 1 way with no comparison group of patients treated in another way.

Articles that did not achieve immediate consensus among the author group were discussed extensively until a consensus was reached. Very few contributions required extensive discussion. Most articles were easily designated as containing Class I, II, or III medical evidence using the criteria set forth by the author group at the initiation of the literature evaluation process (see the "Rating Scheme for the Strength of the Evidence" field).

#### Methods Used to Formulate the Recommendations

Expert Consensus

#### Description of Methods Used to Formulate the Recommendations

The current author group was selected for its expertise in spinal surgery (both neurosurgical and orthopedic), neurotrauma, clinical epidemiology, and, in several cases, prior experience with guideline development. The topics chosen for inclusion in this iteration of these guidelines are contemporary and pertinent to the assessment, evaluation, care, and treatment of patients with acute cervical spine and/or spinal cord injuries.

#### Rating Scheme for the Strength of the Recommendations

Levels of Recommendation

Level	Generally accepted principles for patient management, which reflect a high degree of clinical certainty (usually this requires Class I evidence which directly addresses the clinical questions or overwhelming Class II evidence when circumstances preclude randomized clinical trials)
Level II	Recommendations for patient management which reflect moderate clinical certainty (usually this requires Class II evidence or a strong consensus of Class III evidence)
Level	Other strategies for patient management for which the clinical utility is uncertain (inconclusive or conflicting evidence or opinion)

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Not stated

## Description of Method of Guideline Validation

Not applicable

## **Evidence Supporting the Recommendations**

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

- Accurate neurological examination
- Accurate functional outcome assessment
- Accurate pain assessment
  - Pain severity
  - Physical functioning
  - Emotional functioning

#### Potential Harms

Not stated

# **Qualifying Statements**

### **Qualifying Statements**

- Medical evidence-based guidelines are not meant to be restrictive or to limit a clinician's practice. They chronicle multiple successful treatment options (for example) and stratify the more successful and the less successful strategies based on scientific merit. They are not absolute, "must be followed" rules. This process may identify the most valid and reliable imaging strategy for a given injury, for example, but because of regional or institutional resources, or patient co-morbidity, that particular imaging strategy may not be possible for a patient with that injury. Alternative acceptable imaging options may be more practical or applicable in this hypothetical circumstance.
- Guidelines documents are not tools to be used by external agencies to measure or control the care provided by clinicians. They are not medical-legal instruments or a "set of certainties" that must be followed in the assessment or treatment of the individual pathology in the individual patients we treat. While a powerful and comprehensive resource tool, guidelines and the recommendations contained therein do not necessarily represent "the answer" for the medical and surgical dilemmas faced with many patients.

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

## Implementation Tools

Mobile Device Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

#### **IOM Domain**

Effectiveness

## Identifying Information and Availability

## Bibliographic Source(s)

Hadley MN, Walters BC, Aarabi B, Dhall SS, Gelb DE, Hurlbert RJ, Rozzelle CJ, Ryken TC, Theodore N. Clinical assessment following acute cervical spinal cord injury. In: Guidelines for the management of acute cervical spinal cord injuries. Neurosurgery. 2013 Mar;72(Suppl 2):40-53. [117 references] PubMed

#### Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

2013 Mar

## Guideline Developer(s)

American Association of Neurological Surgeons - Medical Specialty Society

Congress of Neurological Surgeons - Professional Association

## Source(s) of Funding

Congress of Neurological Surgeons

#### Guideline Committee

Guidelines Author Group of the Joint Section of Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons

## Composition of Group That Authored the Guideline

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#### Financial Disclosures/Conflicts of Interest

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this guideline.

#### Guideline Status

This is the current release of the guideline.

### Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) and EPUB for eBook devices from the Neurosurgery Web site

#### Availability of Companion Documents

The following are available:

	Foreword. Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):1. Electronic copies:
	Available in Portable Document Format (PDF) from the Neurosurgery Web site
•	Commentary. Guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):2-3. Electronic
	copies: Available in PDF from the Neurosurgery Web site
•	Introduction to the guidelines for the management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):5-16. Electronic
	copies: Available in PDF from the Neurosurgery Web site
•	Methodology of the guidelines for management of acute cervical spine and spinal cord injuries. Neurosurgery 2013;72(3):17-21. Electronic
	copies: Available in PDF from the Neurosurgery Web site.

#### Patient Resources

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on July 9, 2013. The information was verified by the guideline developer on October 3, 2013.

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